510(k) Summary

510(K) NUMBER: Pending (**Assigned: K082805**)

SUBMITTED BY OWNER: Q Urological Corporation
P.O. Box 793
Natick, MA 01760
781-245-2232

OFFICIAL CONTACT: Scott M. Epstein
President

DATE OF PREPARATION: September 22, 2008 **(Revised November, 2009)**

TRADE NAME AND MODEL OF DEVICE:
pAguaMedicina Structural Hydrogel Pediatric Ureteral Stent, Model Number, NP330-xxx

CLASSIFICATION NAME:
Ureteral Stent - 21 CFR 876.4620; Product Code FAD

CLASSIFICATION PANEL:
Gastroenterology / Urology

SUMMARY STATEMENT:

(Indication for Use Revised--November, 2009)
The Q Urological pAguaMedicina Structural Hydrogel Pediatric Ureteral Stent is used to facilitate temporary internal urinary drainage from the kidney to the bladder and stenting of the ureter in a pediatric patient no less than 2 years old and not more than 12 years old. The stent may be placed endoscopically, percutaneously, or using open surgical techniques. The stent should not be implanted for more than 30 days. This product is not intended as a permanent indwelling device.

The Q Urological Corporation pAguaMedicina Structural Hydrogel Pediatric Ureteral Stent is substantially equivalent to several predicate devices including: the Sof-Flex Pediatric Double Pigtail Ureteral Stent (Cook Urological), the Silhouette Pediatric Ureteral Stent (Applied Medical Resource), the PANAMEX Ureteral Stent (Kingston Technologies) and the Aquasilque Ureteral Stent (American Medical Systems).

Differences between the predicates and the pAguaMedicina Structural Hydrogel Pediatric Ureteral Stent are the profile of the anchorage and the stent material.

When tested against several predicate devices, the anchorage method withstood a significantly greater force before coming dislodged. The anchorage section of the stent by Q Urological Corporation is radiopaque.

The composition of the stent material has been used before in predicate devices. For the pAguaMedicina Structural Hydrogel Pediatric Ureteral Stent this material has been processed by a proprietary method which delivers equivalent technological characteristics. It was tested for biocompatibility in accordance with the suggestions of ISO 10993 for prolonged exposure.

Bench performance testing was selected based on the FDA Guidance for the Content of Premarket Notifications for Ureteral Stents. Testing to determine the anchorage force, elongation and tensile strength, and flow rate of the Q Urological Corporation pAguaMedicina Structural Hydrogel Pediatric Ureteral Stent were conducted and the results compared favorably to those of the predicate devices tested.

In addition, predicate stents for pediatric patients have been cleared for the same size as the pAguaMedicina Structural Hydrogel Pediatric Ureteral Stent.

The Q Corporation pAguaMedicina Structural Hydrogel Pediatric Ureteral Stent has the same intended use as the predicates and has no technological differences which raise new questions of safety and effectiveness and it is at least as safe and effective as the predicates.

Therefore the Q Corporation pAguaMedicina Structural Hydrogel Pediatric Ureteral Stent is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Scott M. Epstein
President
Q Urological Corporation
1E Melvin Street, P.O. Box 793
NATICK MA 01760

JAN 20 2010

Re: K082805
Trade/Device Name: pAguaMedicina Structural Hydrogel Pediatric Ureteral Stent
Regulation Number: 21 CFR §876.4620
Regulation Name: Ureteral stent
Regulatory Class: II
Product Code: FAD
Dated: November 25, 2009
Received: November 27, 2009

Dear Mr. Epstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082805

Device Name: pAguaMedicina Structural Hydrogel Pediatric Ureteral Stent

Indications For Use: pAguaMedicina Structural Hydrogel Pediatric Ureteral Stent is used to facilitate temporary internal urinary drainage from the kidney to the bladder and stenting of the ureter in a pediatric patient no less than 2 years old and not more than 12 years old. The stent may be placed endoscopically, percutaneously, or using open surgical techniques. The stent should not be implanted for more than 30 days. This product is not intended as a permanent indwelling device.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices, Office of Device Evaluation (ODE)
510(k) Number K082805